

Policy Number	CIIACC 036
Title	Research Compliance Policy
Department/Division	Research/IRB — General Administration
Owner	System Director of Research
Approvers	Dr. Bagchi, Pukar Ratti, Phyllis Everage, Francis Kanayo
Review Frequency	Every 3 years
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Purpose

This policy delineates research compliance at CHRISTUS Health

Definitions

Research/trial/study: A systematic investigation designed to produce generalizable knowledge.

Signatory Official (SO): a high-level institutional official who has the authority to represent the institution named in the Federal wide Assurance (FWA) with the Health and Human Services (HHS).

Compliance Auditor (CA): An independent, subject expert responsible for conducting research monitoring. The Compliance Auditor may be a representative from the Regulatory Affairs Department.

Program Director, Revenue Cycle & Research Compliance (Corporate): a research expert that oversees the compliance of the whole research enterprise at CHRISTUS Health.

Monitoring: A non-punitive, constructive, and mentoring process providing an avenue for improving and maintaining good research practice.

Auditing: a strategic examination and verification of research records and conduct to evaluate or improve the rights, safety and welfare of research subjects.

Policy Statement

1. All research conducted on human subjects within CHRISTUS Health irrespective of sponsorship, IRB of record, region, or duration or other pertinent matters are subject to research compliance auditing or monitoring.
2. Research compliance shall comprise of CIIACC Research Compliance Program (lead by research Compliance Auditor) and the corporate Revenue Cycle and Research Compliance (lead by Program Director)

Guidelines

A. Background

The success of research activities or programs across the system requires the active involvement of individuals through participating in training, abiding by established policies and procedures, reporting misconducts or potential violations of regulations and, contributing to process improvement activities that will promote and sustain quality research.

It is the responsibility of each research operating unit or site to conduct research operations in accordance with all applicable laws and regulations and to implement CHRISTUS Health's policies.

- i. Being conducted in compliance with governing federal regulations and CHRISTUS Health policies
 - ii. Being conducted in compliance with approved protocol
 - iii. Being conducted without material changes to the protocol prior to **IRB** approval
- b. **For-cause audits (FCA):** For-cause audit is an extensive study inspection activity during potential or real case serious or continuous non-compliance that results in significant patient harm; over 500 research subjects data breach; any untoward study suspension or termination; any research misconduct and an event that may put the research participants or institution at risk.
 - 1) Objective: For-cause monitoring shall aim at gathering relevant information to present to CIIACC management and the CHRISTUS Health IRB.
 - 2) Audit findings that are found to be unacceptable may draw commensurate measures like disciplinary action, vendor contract cancellation, corrective and preventive action plans among others.

5. **Audit Reports**

Audit findings (if any) are captured in an audit report given to the PI. CIIACC leadership corporate research compliance and other parties as deemed necessary by CIIACC leadership may be provided a copy of the audit report.

Reports with Recommendations typically require response from the principal investigator.

6. **Corporate Audit**

The Program Director, Revenue Cycle & Research Compliance (Corporate), may conduct audits independent of the CIIACC's Research Compliance audit

C. Monitoring

Monitoring is non-audit continuous compliance-focused oversight of research activities via;

- 1. Corrective and preventive action plans (CAPA) Control
- 2. Conflict of Interest (COI) Consult
- 3. Monitoring Report Trend
- 4. Compliance Probe, and
- 5. Close Monitoring List

For definitions of these monitoring activities see Research Compliance Definitions.

D. Corrective & Preventive Action Plans (CAPA)

- 1. CAPA is a document the **PI** shares with compliance auditor especially after for-cause audit and some cases of routine. There are few cases where a CAPA may be requested without an audit due to non-compliance.
- 2. CAPA is especially needed depending on:
 - a. The nature of non-compliance
 - b. The degree of risk to research participants and,
 - c. Occurrence of previous noncompliance, etc.
- 3. The options of possible CAPA that the Regulatory Affairs Department, and/or Signatory Official may consider includes, but is not limited to:
 - a. Modification(s) of the research protocol or consent form.
 - b. Observation of the consenting process.
 - c. Education and mentoring for the **PI** and/or research staff on measures to prevent recurrence.
 - d. Additional resources to support the investigator's research activities.

The responsibilities of the research compliance program include, but not limited to: training or informing research stakeholders about the hazards of research misconduct or non-compliance; conducting audits; monitoring research activities; correcting violations; investigating incidents and complaints by employees and patients; providing regulatory support to IRB members; enforcing policies; reporting to institutional & federal agencies; and appropriately documenting compliance activities and processes.

B. Auditing

Before an audit occurs, the principal investigator and research staff shall be informed via the Notice of Intent (NOI) to audit letter. The NOI letter shall provide all the pertinent information to perform the audit and shall come with a copy of the audit plan, and audit policy.

The following addresses the processes for CIIACC's Research Compliance Program (corporate research audit practices will follow later):

1. Audit Plan

This document shall be included with the NOI letter. It contains the audit objectives, scope, client, activities and criteria and more. Investigators and staff may refer to this document for guidance on detail plan of the audit process.

2. Audit Location

a. Onsite audits: Audits that occur at the site level where research is conducted. The compliance auditor travels locally to the site and physically reviews research records and practices. This is mostly performed during For-Cause Audits (FCA).

b. Remote: Audits that do not require compliance auditor travel to the site or region. This entails a review of requested documents at the system office by the compliance auditor.

3. Audit Records Request

The NOI audit letter shall list and check records requested for review either for onsite or remote audit purposes.

Below is an example of selected records for review in remote auditing:

- | | | |
|---|--|--|
| <input checked="" type="checkbox"/> Signed dated informed consent | <input type="checkbox"/> Documentation and consent process | <input type="checkbox"/> PI eligibility page (drug) |
| <input type="checkbox"/> Inclusion/exclusion criteria page | <input type="checkbox"/> Medical history records | <input type="checkbox"/> Data abstraction sheet |
| <input type="checkbox"/> Delegation of authority log | <input type="checkbox"/> Regulatory documents | <input type="checkbox"/> Drug accountability log |
| <input type="checkbox"/> Screening/enrollment log | <input checked="" type="checkbox"/> AE/SAEs log | <input checked="" type="checkbox"/> Site training log |
| <input checked="" type="checkbox"/> Specimen shipping log | <input checked="" type="checkbox"/> Note to file | <input type="checkbox"/> Audits or inspection report |
| <input type="checkbox"/> Conflict of interest | <input type="checkbox"/> Entire source document | <input type="checkbox"/> FDA 1572 |
| <input type="checkbox"/> Corrective/Preventive Action | <input type="checkbox"/> Site SOP policies | <input type="checkbox"/> Site internal QA process |
| <input type="checkbox"/> Conflict of interest | <input type="checkbox"/> Sponsor eligibility waivers | <input checked="" type="checkbox"/> Monitoring letters |
| <input type="checkbox"/> Signed dated informed consent | <input type="checkbox"/> Correspondence | <input type="checkbox"/> Other |

4. Audit Types

There are two types of audit depending on the audit objective:

a. Routine audits (RA): Also known as not-for-cause audits. Routine audits is a non-punitive, process-improvement driven study review that provide valuable feedback to research staff on compliance with regulations that require protection of human subjects and adherence to study protocol.

1) All approved protocols irrespective of the IRB of record are subject to this audit type.

2) Each Objective: The routine audit serves as a tool to periodically assess whether human subjects research is:

4. A lesser CAPA can also take the form of a Statement of Commitment. In this case, a CRC or investigator provides the compliance auditor a written commitment to adhere to study protocol or abide by applicable laws and regulations. If an investigator fails to abide by his Statement of Commitment, it can elicit a CAPA or an audit.

References

21 CFR Part 11, Electronic Records; Electronic Signatures
21 CFR Part 50, Protection Human Subjects
21 CFR Part 312, Investigational New Drug Application
21 CFR Part 812, Investigational Device Application
21 CFR part 56.109(b)(f)
21 CFR 56.109
21 CFR 50
45 CFR Parts 160 and 164

Approved By:

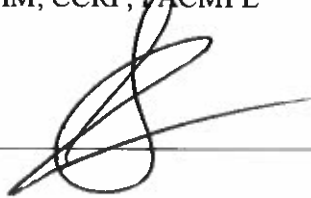


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30 JULY 2018

Date

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8/14/18

Date